

SIX AREAS OF SANITATION & THEIR RELATIONSHIP TO THE REQUIREMENTS OF THE FOOD GMPS & PMO.

For the most part, compliance with good manufacturing practices and sanitation requirements are the foundation for safe food production. The table that follows takes each of the six sanitation areas and relates them to specific citations in FDA's 21 CFR Part 110, Good Manufacturing Practice regulations and the Pasteurized Milk Ordinance (PMO). Additional guidance on GMPs and requirements for the sanitary production and storage of food products can be found in FDA's "CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOODS" 21 CFR Part 110, and in the FDA "Pasteurized Milk Ordinance (PMO)".

Six Areas of Sanitation (SSOP's)	Corresponding Part 110 Requirements	Corresponding PMO Sections (Section 7 unless otherwise noted)
(1) Safety of process water	110.37(a); .110.80(a)(1)&(b)(16): Process water safe and of adequate sanitary quality; water used for washing; rinsing; or conveying of safe and adequate sanitary quality; water used for ice manufacture of safe and adequate sanitary quality ----- ----- 110.37(b)(5): No cross connections between sewer or wastewater and process water	7p (water supply), Appendix D (Standards for Water Sources)
(2) Condition and cleanliness of food contact surfaces	110.40(a)&(b): Food contact surfaces designed, fabricated, maintained, and installed to be environment of use and cleaning compounds; smoothly bonded seams. 110.35(d)(2); .80(b)(1) & (b)(10) & (b)13(ii): When cleaning is necessary to protect against introduction of microorganisms, clean and sanitize before use, after interruptions, and as necessary---. 110.10(b)(1)&(5): Gloves should be impermeable, clean, and sanitary; outer garments suitable	10p (sanitary piping), 11p (Construction and repair of containers and equipment, 12p (Cleaning and sanitizing of containers and equipment)
(3) Prevention of cross contamination.	110.10(b)&(b)(2)&(b)(3)&(b)(4)&(b)(7)& (b)(8) &(b)(9); 110.80(b)(6)& (b)(13)(v): Food handlers conform to hygienic practices to the extent necessary to prevent contamination; maintain adequate personal cleanliness; wash, and sanitize if necessary, hands before start work, after absence from work station, and when become contaminated; taking precautions as necessary to protect against contamination with microorganisms; effective measures to prevent finished product contamination by raw materials, other ingredients, refuse; remove jewelry that cannot be sanitized; abstaining from eating, chewing gum, drinking, or using tobacco near exposed food or equipment; storing clothing or personal items away from exposed food and equipment.	15p(B) (cross connections)
Six Areas of Sanitation (SSOP's)	Corresponding Part 110 Requirements	Corresponding PMO Sections (Section 7 unless otherwise noted)
	110.20(b)(1)&(2)&(4): Plant design must reduce potential for contamination of food, food contact surfaces, and packaging	

	<p>material and must permit employees to protect against contamination of food from clothing or personal contact; separation of operations.</p> <p>110.37(e)&(e)(1) -(4): Hand washing and, where appropriate, hand sanitizing facilities should be at each location where good sanitary practice dictates their use; effective hand-cleaning and sanitizing preparations; water at suitable temperature; sanitary towel service or suitable drying devices; <u>designed to prevent recontamination-----</u>.</p> <p>110.37(c)&(d): Adequate sewage disposal system; adequate, readily accessible toilet facilities; maintained in sanitary condition; self-closing doors; protect food from airborne contamination</p>	
<p>(4) Protection of food, food packaging material, and food contact surfaces from adulteration.</p>	<p>110.40(a);.110.80&(a)(5)&(a)(7)&(b)(5) &(b)(7)&(b)(10)&(b)(12)&(b) (13); 110.93: Design, construction, and use of equipment precludes adulteration of food with lubricants, fuel, metal fragments, contaminated water, or other contaminants; all reasonable measures to ensure that production methods do not contribute contamination; raw materials held to protect against contamination; work-in-progress handled to protect against contamination; equipment protects food from contamination; mechanical steps protect from contamination; batters, breadings, sauces, dressing, etc. protected from contamination; filling, assembly, packaging, and other operations protect food from contamination; storage and transportation protect the food from contamination-----</p> <p>--</p> <p>110.20(b)(4);.80(b)(10)&(b)(12) (iv): Drip or condensate from fixtures, ducts and pipes does not contaminate food, food contact surfaces, or packaging material; Adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food should be provided-</p> <p>110.40(g): Compressed air or other gases mechanically introduced treated to prevent contamination of food.</p>	<p>13p (storage of cleaned containers and equipment), 14p (storage of single service containers), 15p(A) (protection from contamination), 18p (bottling and packaging), 19p (capping), 21 (clean properly constructed vehicles)</p>

Six Areas of Sanitation (SSOP's)	Corresponding Part 110 Requirements	Corresponding PMO Sections (Section 7 unless otherwise noted)
	110.35(b)(2)&(c): Toxic cleaning compounds, sanitizing agents, and pesticides identified, held, and stored in a manner that protects food, food contact surfaces, and packaging material from contamination; all relevant regulations for their use followed; pesticides used only when food, food contact surfaces, and packaging material protected from contamination.	
(5) Control of employee health conditions and hygiene that could result in microbiological contamination of food, food packaging material, and food contact surfaces..	110.10(a): Food handler who has illness or open lesion, or other source of microbiological contamination that presents reasonable possibility of contamination of food, food contact surface, or packaging material excluded from such operations.	6p (toilet facilities), 8p (hand-washing facilities), 20p (personnel cleanliness) , Section 13 (Personnel Health), Section 14 (Procedure When Infection or High Risk of Infection is Discovered)
(6) Exclusion of pests.	110.35(c): No pests shall be allowed in any area of a food plant.	3p (outer openings adequately protected against entrance of pests), 9p (no evidence of pests in milk plant), 22p (surroundings free of harborages)

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